

DSJ1&2-PR Exh 531

SUSPICIOUS ORDER MONITORING TEAM CHARTER

Updated 04/07/11

Team Start Date	03/28/08
Team Leader	Karen Harper
Team Champion	Tom Berry (as of 06/10)
Business Unit	Pharmaceuticals

Process Description

Maintain regulatory compliance with DEA mandated Suspicious Order Monitoring (SOM) as stated in 21CFR 1301.74(b). Upgrade Mallinckrodt's existing SOM program to meet/exceed DEA requirements and to adapt program based upon changing trends in diversion and abuse of controlled substances.

Team Structure and Membership

SOM Leadership Team

Frequency of meetings: once per month

Members: Pat Duft, V-P Legal
Don Lohman, Associate General Counsel
Bill Ratliff, Director of Security
Karen Harper, Sr. Controlled Substance Compliance Manager

SOM Steering Committee

Frequency of meetings: once per quarter

Members: Pat Duft, V-P Legal
Don Lohman, Associate General Counsel
Bill Ratliff, Director of Security
Karen Harper, Sr. Controlled Substance Compliance Manager
Eileen Spaulding, Sr. Controlled Substance Compliance Coordinator
Mike Gunning, V-P Commercial Operation
Jane Williams, V-P Generic Sales
Bob Lesnak, V-P Addiction Therapy
Jason Jones, V-P Brand Sales
Ginger Collier, Sr. Product Manager, Marketing
George Saffold, Customer Service Director
Jim Rausch, Customer Service Manager
Kathy Schaefer, V-P Controller
Carol Svejkosky, Finance & Administration Director
Suzanne Pea, Customer Accounts Director
Susan Moore, Director of Finance
Art Morelli, Director of Medical Affairs
Debbie Digby, Sr. Analyst, Contracts & Analysis

SOM Subcommittees

Frequency of meetings: as needed

Subcommittee	Name
	Director Order Monitoring
	Indirect Customer Review
	Distributor Audit
	Customer Checklist



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